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Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT,
Individually And As Guardians Ad Litem For
JASON DAUBERT, and ANITA DE YOUNG, Individually
And As Guardian Ad Litem For ERIC SCHULLER
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.
Respondent.

**On Writ Of Certiorari To The
United States Court Of Appeals For The Ninth Circuit**

**BRIEF OF AMICI CURIAE
DARYL E. CHUBIN, Ph.D.
EDWARD J. HACKETT, Ph.D.
DAVID MICHAEL OZONOFF, M.D., M.P.H.
RICHARD W. CLAPP, Sc.D., M.P.H.
IN SUPPORT OF PETITIONERS**

NICOLE SCHULTHEIS, ESQ.
NICOLE SCHULTHEIS, P.A.
201 N. CHARLES ST., SUITE 1630
BALTIMORE, MD 21201
(410) 547-1771

RON SIMON, ESQ.*
CONNERTON, RAY AND SIMON
1920 L ST., SUITE 400
WASHINGTON, D.C. 20036
(202) 466-6790
**Counsel of Record*

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THE INTERESTS OF THE *AMICI CURIAE*

All four amici are scholars with wide-ranging experience in the fields of medicine, epidemiology, history of medicine, history of science, and sociology of knowledge. **Daryl E. Chubin**, a Senior Associate and Project Director in the Science, Education, and Transportation Program, Office of Technology Assessment, U.S. Congress, and **Edward J. Hackett**, an Associate Professor in the Department of Science and Technology Studies at the Rensselaer Polytechnic Institute, are the co-authors of PEERLESS REVIEW: PEER REVIEW AND U.S. SCIENCE POLICY (1990), which has been widely hailed as the most definitive text on the strengths, weaknesses, operations, purposes, and principles of and the controversies surrounding the peer review system. Both Chubin and Hackett have participated in the peer review system as authors published by peer review journals, as "referees" who have reviewed articles submitted to such journals by other writers, and as editors of such journals, as well as speaking and publishing at various scholarly, but not peer review, fora.[1]

David Michael Ozonoff is the Chair of the Department of Environmental Health at the Boston University School of Public Health and Professor of Public Health as well a Professor in the Department of Socio-Medical Science and Community Medicine at the Boston University School of Medicine. **Richard W. Clapp** is the Director of the Center for Environmental Health Studies for John Snow, Inc. in Boston, an Assistant Clinical Professor at Tufts University School of Medicine and an Adjunct Assistant Professor at Boston University School of Public Health. Like Chubin and Hackett, Ozonoff and Clapp have participated in the peer review system as authors, editors, and referees, and, like their fellow *amici*, have spoken and written widely at a variety of scholarly, but not peer review, fora. In addition, both Ozonoff and Clapp have provided testimony as expert witnesses at numerous trials and depositions.

None of the *amici* have an interest in either the outcome of this case or the outcome of other so-called "Bendectin cases". *Amici* seek to advise the Court that the decisions below were premised on a fundamental misunderstanding of the peer review

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[1] A more detailed description of the positions held by and qualifications of the amici are set forth in the attached Appendix.

system, a misconception that has the potential of distorting both the way trials are conducted and the way in which the peer review system operates. If federal courts intend to base decision regarding the admissibility of expert opinion testimony on determinations made by the editors and referees of peer review journals, these courts ought understand how the peer review journal system functions and the weaknesses as well as the strengths of that system. The need to understand these matters transcends the interests of the parties in this case and the unique perspectives of the *amici* might not otherwise be brought to the attention of the Court.[2]

SUMMARY OF ARGUMENT

The peer review system[3] has many virtues. Serving as a litmus test for truth, as a guarantor of scientific certainty, and as the gatekeeper for expert witnesses for the litigation process are not among them. The peer review system was not designed to serve those functions, makes no claims to do so, and, at least as presently instituted, is incapable of performing those tasks. The purposes of the journal peer review system in science are to screen for obvious errors in methodology and reasoning, and to ensure that the research is novel and "important." The peer review system serves those purposes well, but, like other tools, its utility is marginalized when it is employed for purposes for which it was not designed. For example, the peer review system is not a truth certification process, nor does it guarantee that the particular data, research and analytical methodologies, or conclusions of the

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[2] Counsel for all parties have consented to the filing of this *amicus* brief. Letters of consent have been filed with the Clerk of the Court.

[3] The term "peer review system" is used to describe the system of submitting, reviewing (or refereeing), and editing papers intended for publication to "peer review journals," as distinct from the system of using peer review referees to judge proposals for research grants, *i.e.*, "grants peer review." See Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 1-15 (1990).

accepted papers represent the consensus opinion of the relevant community.

Each of the amici has carefully read the decisions filed by the United States Court of Appeals for the Ninth Circuit and the United States District Court for the Southern District of California in this case as well as the petition for certiorari, the respondent's opposition to the petition, and the petitioners' reply brief. We are troubled by the portions of those decisions that purport to describe and use the peer review system as tools in the litigation process. We are troubled by the lower courts' decision to rely -- exclusively -- on peer review journals to determine whether an expert witness can be allowed to testify before a jury and what he or she may say if allowed to testify. We believe that the lower courts' misunderstanding of the peer review system led them to devise and ordain two mischievous presumptions: an apparently rebuttable presumption that anything that is published in a peer review journal is "good science" and therefore admissible; and, conversely, an evidently irrebuttable presumption that unless a theory, fact, and analysis has been previously published in a peer review journal such ideas and information cannot be "good science" and cannot form the basis for admissible expert testimony.

We are also disturbed by the fact that the lower courts rendered those decisions without an accurate understanding of the peer review system and, apparently, without any factual background concerning that system. We cannot understand why the lower courts made such a choice and we have read nothing in the lower courts' decisions that explains their reasoning.[4]

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[4] We were surprised to see that the courts below did not cite a single scientific authority in support of their rulings on these points. The sole authority mentioned, Peter Huber, is not known to be either a scientist or a scholar. Indeed, it seems as if the zeal with which the courts below embraced the peer review system can only be explained by their obliviousness about the controversies about the peer review system that have roiled the academic and scientific communities for at least the last half-dozen years. Thus, "there is mounting evidence that peer review in the United States is not functioning well, and there is growing concern among scientists and policymakers about the soundness of the peer review system." Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990), at 1. SEE ALSO THE PROCEEDINGS OF THE FIRST INTERNATIONAL CONFERENCE ON PEER REVIEW IN

(continued...)

Before we endeavor to suggest where the lower courts erred in the understanding of the peer review system and before we describe what we believe to be the real strengths and not inconsiderable weaknesses of that system, we must confess that we are unqualified to offer this Court any guidance concerning the legal issues presented by the petition for certiorari filed in this case: whether the common law test for admissibility of expert opinion testimony that originated with *Frye v. United States*, 293 F. 1013 (1923), survived Congress' enactment of a rule of evidence that deals with the same subject, whether federal judges possess some sort of inherent power that they can employ to supplement whatever rules are enacted by Congress, and whether the U.S. Constitution authorizes federal judges to devolve to the editors of peer review journals (and to the anonymous referees who are hand-picked by those editors) decisions about what is (and what is not) so-called "good science" and regarding which expert witnesses can be allowed to testify in criminal and civil cases.[5]

Moreover, although we have made some efforts to familiarize ourselves with the underlying factual controversy in this case (having gone so far as to read, among other things, the affidavits and curriculum vitae submitted to the District Court by the plaintiffs' experts and the defendant's expert), we also acknowledge that we can offer no help in helping to decide whether Bendectin can cause birth defects, in general, and whether Bendectin caused the birth defects that the plaintiffs-petitioners allegedly suffered, in particular. Thus, if we were today to be seated as jurors in this case we could not be say who should prevail

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[4](...continued)
BIOMEDICAL RESEARCH, May 10-12, 1989 (Many of the papers presented at the conference were printed in an issue of the Journal of the American Medical Association specially devoted to that topic. 263 J. AMER. MED. ASS'N No. 10 (1990).)

[5] We do think it odd, however, that federal judges, who are pledged to uphold a Constitution that emphasizes such principles of due process of law as public access and accountability should be so eager to consign threshold questions of who can testify and what they can say to the self-selected editors of private journals, whose decisions are largely shrouded from view and totally insusceptible to appeals.

-- not unless we had heard all the experts testify and not unless we had seen these same experts cross-examined under oath.

Why, then, have we been vexed to involve ourselves in this matter and why do we think that the Justices of this Court should pay any mind to what we have to say? The reason is simple. We are knowledgeable about the peer review process and its useful contributions to the dissemination of scientific learning. But, because we appreciate the system's limitations as well as its advantages, we believe that the burden placed by the lower courts on the peer review system is a weight that system cannot bear. If we were sitting on a jury in a case such as this, we assuredly would think it important to learn what articles had been written, pro and con, about the issues in dispute. Nevertheless, in general, we do not think that the fact that one expert could point to a published article in support of his views and the fact that another expert could not cite a published article in support of her views would be the acid test in our decision-making. We do not think that such facts should be the acid test for the decision-making.

Such facts *might influence*, to a greater or lesser degree, our preliminary decision about which expert(s) to believe, but we would not allow our decisions on this sort of threshold issue to turn on a single fact such as publication or non-publication. In our view, the lower courts did not truly comprehend how the peer review system does (and does not) work, how well (and how poorly) the system operates, and what are the system's true strengths (and its not inconsiderable weaknesses). If the lower courts had understood the system as we do they would not have relied on it as a shortcut for and they certainly would not have proposed to rely on it as he exclusive indicator of reliable and valid expert testimony.

Although it is appropriate for courts to use the peer review system to help guide the decisions of judges and jurors, courts should not rely on solitary facts -- such as publication, multiple publication, publication in prestigious journals, or non-publication -- as the exclusive determinant of whether an expert has anything useful to say and whether that expert should be allowed to testify. The temptation to rely upon the peer review system to provide a quick fix for the sometimes irritating and frequently time-consuming problems presented by cases that involve complicated questions of science may be a understandable one. But this impulse to rely

exclusively on peer review literature (and its interpreters), like many ideas born of frustration, should be resisted. This temptation should be resisted because the allure of relying on the peer review system is based on ignorance of and myths about that system, not knowledge and understanding of it. The lure of the peer review system stems from six largely erroneous beliefs, myths that gain no validity from the fact that they may be widely held. As discussed at length below, none of these myths can withstand serious scrutiny.

First, the peer review system is not intended to yield "the truth, the whole truth, and nothing but the truth." ***Second***, peer review journals do not replicate and verify the experiments, research and analytical techniques, or data reported in the papers submitted for publication. ***Third***, peer review journals do not warrant that the ideas and information contained in the articles they publish are accurate, valid, certain, reliable, or true, or otherwise amount to "good science." ***Fourth***, the mere fact of publication does not mean that the ideas and information reported in an article are "generally accepted" by, or represent the "consensus" views of, the relevant academic community. ***Fifth***, conversely, the fact that ideas and information have not been published in a peer review journal does not mean that they are not "generally accepted", or that they are "generally rejected", or that they cannot represent "good science." ***Finally***, the peer review system should not be regarded as more rigorous and reliable than the jury system's use of cross-examination. For these reasons, the courts should not rely exclusively on peer review literature, but should consider peer review literature in conjunction with other materials and with expert testimony.

In sum, the courts should not put all of their eggs in the peer review basket.

ARGUMENT

I. CONTRARY TO POPULAR MYTH, THE PURPOSES AND DESIGN OF THE PEER REVIEW SYSTEM ARE *NOT* TO PRODUCE "THE TRUTH, THE WHOLE TRUTH, AND NOTHING BUT THE TRUTH."

Although witnesses are obliged to swear to "tell the truth, the whole truth, and nothing but the truth," the litigation process overall does not seek absolute truth but, instead, a much more modest, yet still quite challenging goal -- providing justice to the parties to a case.[6] Similarly, although the overarching goal of the peer review system may be to add to the total sum of scientific knowledge and to the grand scheme of scientific understanding of the universe, the practical and immediate purposes, and the concomitant operation, of the peer review system are much more modest. "Briefly defined, peer review is an organized method for evaluating scientific work which is used by scientists to certify the correctness of procedures, establish the plausibility of results, and allocate scarce resources (such as journal space, research funds, recognition, and special honor)." Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 2 (1990). The primary goal of the peer review system is to provide a relatively permanent and readily accessible documentary record of ongoing scientific research and analysis, that is, printed reports rather than anecdotal or apocryphal accounts, and thus to facilitate the development and exchange of ideas.[7] The

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[6] If our legal system genuinely aimed for "the whole truth and nothing but the truth," it would have to jettison numerous rules, traditions, and doctrine that substantially interfered with the fulfillment of that goal. Thus, the courts would need to repudiate virtually all privileges (whose major function is to limit the information that is available to the trier of fact), statutes of limitation and statutes of repose, all limitations on discovery, in both civil and criminal cases, as well as such constitutional criminal law precepts as the Exclusionary Rule and the *Miranda* doctrine.

[7] The incidental purpose of the peer review system is to add to the reputations and enhance the careers of authors, referees, and editors, thereby (continued...)

peer review system is designed to compel authors of such reports to comply with certain minimal formal and stylistic standards in order to weed out essays that appear facially implausible, indefensible, erroneous, fallacious, or fraudulent. The articles that survive the screening process are presented in a standardized format in journals that are made readily available to all scholars and practitioners in a particular discipline, who may then use them in their own work or may challenge them in their own writing, *e.g.*, by attempting to replicate the experiments described or to reanalyze the results reported. Thus, the peer review system is designed to provide a common and convenient *starting point* for scientific debate, not the *final summation* of existing scientific knowledge.[8]

In a nutshell, the peer review system is not designed, and does not function, to add absolutely true, complete, and definitive chapters to the mythical encyclopedia of knowledge. Instead, the peer review system provides a more practical and still extremely valuable service – to furnish, in a timely fashion, interim progress reports of ongoing research experiments, promising investigatory techniques and methodological protocols, useful analytical tools, interesting findings, or provocative hypotheses. The provisional nature of science "truths" is reflected in the fact that peer review journals welcome, and frequently publish, articles, comments, and letters to the editor that are critical of the initial article. Thus, each article stands not as the final word on a given subject but as an invitation to or part of a continuing debate, a never-ending

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[7](...continued)
helping them to obtain research grants from government agencies, science foundations, and industrial companies, to win fellowships and prizes, or to gain tenure and promotion.

[8] In this respect, as in a number of others, the peer review system resembles the law review structure. Although there are some rather significant differences (to give but two examples: (1) articles submitted to law reviews are vetted by apprentice student-lawyers, while manuscripts tendered to peer review journals are sifted by experienced scientists; and (2) teams of law review editors spend endless hours in painstaking efforts to check the accuracy of every cite and footnote, while peer review referees can afford to spend no more than a few scant hours in assessing the facial plausibility of a manuscript), the two systems share at least one important feature – neither hold themselves out as the quintessence of professional knowledge and wisdom.

dialogue. As Niels Bohr, one of the great theoretical physicists of the 20th century endlessly reminded his colleagues: "Every sentence I utter must be understood not as an affirmation, but as a question."

The contingent nature of the reports that are published additionally reflects the ever-evolving nature of scientific inquiry, knowledge, and techniques. Science is not a static enterprise and does not stand as a timeless body of fixed truths. Instead, the corpus of scientific knowledge consists of a set of historically-bounded and ever-changing research results that are subject not only to selection, qualification, and interpretation but virtually constant reinterpretation and reanalysis.[9] It is vast oversimplification to suggest that new facts are simply added to old facts to construct an ever-larger temple of scientific knowledge in the same way that additional bricks can be piled atop already laid bricks to form a taller wall. There are no absolute, certain truths in science. As Sir William Osler noted: "No human being is constituted to know the truth, the whole truth, and nothing but the truth; and even the best of men must be content with fragments, with partial glimpses, never the full fruition." THE STUDENT LIFE 122 (1919).

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[9] Significantly, historians of science have emphasized that the path to knowledge is not serene, uncomplicated, or predictable. Thus: "The growth of science represents nothing like an unbroken, steadily ascending progression carrying humanity on its shoulders, as it were. It would be far more realistic to think of the history of science as a continuous, sometimes desperate struggle. . . . To think of the evolution of science as a straightforward continuum, or to associate science automatically with progress, involves a profound misunderstanding of the relationship between science and history – if not of the nature of the historic process itself." Thomas Goldstein, THE DAWN OF MODERN SCIENCE (1980), at 245-46. *See generally* Thomas S. Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (2d ed. 1970), a seminal work that "has had a wider academic influence [in any field] than any other book of the last twenty years", PARADIGMS & REVOLUTIONS: APPLICATIONS AND APPRAISALS OF THOMAS KUHN'S PHILOSOPHY OF SCIENCE, Garry Gutting, ed. (1980), at v.

II. CONTRARY TO GENERALLY ACCEPTED BELIEFS, THE EDITORS OF A PEER REVIEW JOURNAL AND THE REFEREES PICKED BY SUCH EDITORS TO REVIEW A SUBMITTED MANUSCRIPT DO NOT REPLICATE AND VERIFY THE EXPERIMENTS, TECHNIQUES, ANALYSES, OR DATA REPORTED IN SUCH MANUSCRIPTS

The myth prevails, at least among non-scientists, that the peer review system subjects articles submitted for publication to scrutiny at least as exacting as that of a recipe submitted to GOURMET magazine, a new model car reviewed by the professional drivers and automotive engineers employed by CAR AND DRIVER, or a toaster tested by the editors of CONSUMERS REPORTS. Would that it were so. Although the abilities of the editors and referees of peer review journals are presumptively higher than the talents of those persons who critique recipes, recreation vehicles, and refrigerators (and although the issues are doubtlessly more transcendentally important), the resources -- lab space and testing equipment, money, and time -- available to part-time peer review editors and unpaid volunteer referees for the purpose of scrutinizing the work of other scientists are far less than enjoyed the persons employed by cooking, car, and consumer magazines. Given these stubborn handicaps, peer review referees and editors limit their assessment of submitted articles to such matters *as style*, *plausibility*, and *defensibility*; they do not duplicate experiments from scratch or plow through reams of computer-generated data in order to guarantee *accuracy* or *veracity* or *certainty*. Once again, whatever their desire to do so, they are hampered by financial constraints, and, as noted below, occasionally by ethical restrictions, too.

THE MECHANICS OF THE JOURNAL PEER REVIEW SYSTEM

In order to fully understand how the peer review system operates -- what it does and does not do and what it is and is not capable of doing -- one should know steps leading to the submission of a manuscript, and the mechanics of how it is treated once

it reaches the editor of the journal.[10] Research is a continuing process and it is rare that any particular project has a definite end. Most presentations of the scientific projects, therefore, represent interim progress reports rather than final summaries that analyze all data, address all concerns, and resolve all questions. Accordingly, the decision of whether to publish an interim report to the scientific community by way of a peer review article and, if so, what, where, and when to publish is far more complicated than is popularly supposed.

As a general rule, however, when, in the opinion of the principal investigator(s), a research project has obtained a preordained or otherwise significant result, the progress is written into a manuscript. Upon reviewing the manuscript, the investigators decide, based upon prior experience, which journals are most likely to publish the paper. Assuming that there is more than one such journal, the paper usually is sent first to the editor of the journal with the most prestige or the largest circulation.

Once the submitted paper is received by the journal editor, the formal peer review process begins. The mechanics of peer review vary somewhat from discipline to discipline and from journal to journal, but can be summarized without too much loss of accuracy for the present purposes. Generally, the editor-in-chief or one of his designees has unfettered discretion to select one or two (rarely more) expert referees to pass judgement on the paper. The referees receive the paper together with short checklist on which to score obvious errors, style, length, and plausibility; the referees are commonly given no more than two weeks to return their tally, along with their comments and recommendation for or against publication. This two week period would hardly be sufficient time for the referees to replicate the research, even if

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[10] It should be noted that although the procedures of the review process vary somewhat from journal to journal, the general protocols are made clear to potential authors. Moreover, although the substance of a referee's comments are eventually made known to the author, the identity, affiliations, credentials, and potential biases or conflicts of those reviewers are almost invariably shrouded in cloaks of confidentiality. Thus, although the peer review system may not be a completely closed and secretive procedure, it is generally a one-sided anonymous enterprise. Accordingly, what happens to a manuscript after an editor turns it over to designated referees is virtually immune to objective study.

they were so inclined, even if they possessed the necessary facilities, and even if their own professional lives left them with nothing else to do.

As it happens, however, the unpaid volunteer referees are almost invariably preoccupied with their own research, writing, and teaching and, as a result, typically can dedicate only a few hours *(averaging only 2.4 hours for each manuscript submitted to four of the most influential medical/public health/epidemiological journals)* to read and evaluate the work. In light of these constraints, the referees very rarely, if ever, undertake a rudimentary reanalysis of the data, the experimental or analytical methodology, and the conclusions.[11] Indeed, even *after* a paper has been published, it is rare that scientists will spend their time and money to replicate the results of other scientists – unless they intend disprove the experiments.

Independent replication and verification of a scientific paper – *before publication*, by peer review referees, or *after publication*, by scientists in the field -- may be the ideal; this ideal is, however, rarely achieved in practice. Indeed, the gap between the real and the ideal appears to be widening by the year, as the growing complexity and expense of modern research, and the increasing pressure to publish new results in order to obtain or retain funding

[11] Alfred Yankauer, *Who Are the Peer Reviewers and How Much Do They Review?*, 263 J. OF THE AMER. MED. ASS'N 1338, 1339 (March 9, 1990) (the referees reviewed papers submitted to the NEW ENGLAND JOURNAL OF MEDICINE, the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION THE AMERICAN JOURNAL OF EPIDEMIOLOGY, and the AMERICAN JOURNAL OF PUBLIC HEALTH. *See also* Stephen Lock and Jane Smith, *What Do Peer Reviewers Do?*, 263 J. OF THE AMER. MED. ASS'N 1341, 1342 (1990) (referees for the BRITISH MEDICAL JOURNAL averaged less than two hours reviewing each paper submitted for publication).

for one's own research.[12] Even where replication may be fiscally possible it may be ethically unimaginable.[13]

II. CONTRARY TO THE "GENERALLY ACCEPTED" MYTH, PUBLICATION OF AN ARTICLE IN A PEER REVIEW JOURNAL IS NO ASSURANCE THAT THE RESEARCH, DATA, METHODOLOGIES, ANALYSES, OR CONCLUSIONS DESCRIBED THEREIN ARE TRUE, ACCURATE, VALID, RELIABLE, OR CERTAIN OR THAT THEY REPRESENT "GOOD SCIENCE"

In service of the scientific publication system, the peer review system aims to serve as a mechanism for the timely, widespread, and relatively inexpensive dissemination of information – research, data, methodologies, analyses, or conclusions – produced by some scientists that might be useful to other scientists. "Peer review simultaneously serves several values that are not entirely in harmony. As a *process*, peer review is expected to operate according to values of fairness and expediency, yet its *product* is to be trustworthy, high-quality, innovative knowledge." Chubin and Hackett, *supra*, at 3. In the pursuit of these twin, and somewhat inherently contradictory, goals of providing useful information to as many scientists as possible and as quickly and as cheaply possible, the peer review system is necessarily obliged to make some difficult choices and to accept some perfectly under-

[12] For example, it is theoretically possible but financially inconceivable for referees to independently replicate week-long experimental runs conducted by particle physicists using such mammoth machines as the Fermilab Nuclear Accelerator.

[13] During the 1950s, government scientists knowingly exposed soldiers and sailors to atomic blasts in an effort to gauge the effects of such high doses of radiation on troop performance and morale. Such experiments have since been widely denounced and, in fact, have been the basis of numerous lawsuits, some of which have reached this Court. It is beyond comprehension that any reputable scientist would attempt to replicate these tests today, and certainly not for solitary purpose of verifying reported test results previously submitted for publication to a peer review journal.

standable compromises. "There is no assurance that the process will yield the product; to the contrary, the process may interfere with efforts to secure the product." *Id.*

For example, the peer review system could decide to guarantee, as much as humanly possible, the accuracy, validity, or reliability -- the truth or certainty -- of published articles. To do so, however, might require journals not only to enlist more volunteer referees but actually to hire full-time professional staffs so as to undertake far more difficult, expensive, and time-consuming attempts to replicate the work presented in manuscripts. If the editors followed this course they could more confidently assure readers that the papers published were accurate and true; at the same time, the editors would be obliged to alert their subscribers to the likelihood that fewer papers could scrutinized and published, that such papers could not be published quickly, and, furthermore, that prohibitive price hikes would almost certainly be necessary to defray the vastly-increased cost of independent replication and verification.

At the other extreme, editors might drastically cut costs and minimize delays by publishing the scientific equivalent of a supermarket tabloid -- that is, to print whatever came over the transom, regardless of provenance and regardless of facial implausibility, under the rationale that the readers themselves could sort it all out. Obviously, a middle course has been chosen by most editors and most journals. The point is that in choosing this middle course, compromise is inevitable.

The result of this compromise between absolute certainty, on the one hand, and absolute speed and absolute economy, on the other, this tension between selectivity and sensitivity -- in brief, the tradeoff between filters course and fine -- is that mistakes become inevitable and that erroneous, misleading, and fraudulent reports are sometimes published. The peer review system is not the perfectly reliable mechanism some of its champions claim it to be.

Indeed, some observers have declaimed that many journals rather routinely ignore or tolerate, but in any event reproduce, inaccurate statistics. Thus, as early as 1966, an article in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION disclosed that an analysis of the quality of statistics reports that had appeared in ten different medical peer review journals "suggest[ed] that from a statistical viewpoint, [only] 41 (28%) of 149 [published] studies

were acceptable, 7 (5%) should have been rejected, and 101 (68%) should have been revised before publication," that is, only that submitted manuscripts contained significant errors but that these errors went undetected (or at least uncorrected) by the editors and referees of those ten medical journals. Martin J. Gardner and Jane Bond, *An Exploratory Study of Statistical Assessment of Papers Published in the BRITISH MEDICAL JOURNAL*, 263 J. AM. MED. ASS'N 1355 (1990), *citing* S. Schor and I. Karten, *Statistical Evaluation of Medical Journal Manuscripts*, 195 J. AM. MED. ASS'N 145-50 (1966). Gardner's and Bond's own and more recent study of peer review articles published in the distinguished BRITISH MEDICAL JOURNAL revealed equally alarming results -- only 11% of incoming manuscripts contained accurate statistical reports; that figure improved to 84% after publication. *Id.* (Although some may find such improvement reassuring, one doubts that praise would be heaped on a truck driver who made significant mistakes only 16% of the time, let alone an airline pilot.)

To make matters worse, many if not most journals do not do what the BRITISH MEDICAL JOURNAL routinely does -- independently assess and correct the statistics cited in articles selected for publication. We have good reason to worry what happens to the articles rejected for publication, whether, as is commonly the case, they were submitted to less prestigious and less demanding journals, where the editors and referees lack the time or inclination to check for statistical accuracy[14] and where the articles might eventually be published.[15]

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[14] Thus, a recent survey revealed that although statistical analyses were prominent in 54.1% to 72.7% of the articles published in a sample of American biomedical journals (depending on the classification of the journals by the researchers), the percentage of journals that "always or usually use a statistical review" ranged from 30.5% to 37.5%. Ann C. Weller, *Editorial Peer Review in US Medical Journals*, 263 J. OF THE AMER. MED. ASS'N 1344 (1990).

[15] Another recent study involved sending 25 manuscripts that had been accepted for publication, after review and revision, by the JOURNAL OF PEDIATRICS (but not published at the time) to two additional referees for evaluation. Joseph M. Garfunkel, Martin H. Ulshen, Harvey J. Hamrick, Edward E. Lawson, *Problems Identified by Secondary Review of Accepted Manuscripts*, 263 J. AM. MED. ASS'N 1369 (1990). The researchers discovered that, although

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The failure of peer review journals to adequately screen out false, substandard, or fraudulent reports might be excusable if the journals did a creditable job of subsequently informing their readers about the existence of the published mistakes (and the dangers of relying on reports containing such flaws) once the errors were noticed. Unfortunately, the journals do not do much better after the fact than they do before.[16]

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[15](...continued)
there was substantial agreement between the first and second set of reviewers, "the initial two-part review failed to identify a significant number of concerns that probably should have been corrected, or at least addressed, before publication." *Id.*, at 1370. Still another study checked 150 randomly selected citations and quotations taken from articles published in three medical journals. James T. Evans, Howard I. Nadjari, and Sherry A. Burchell, *Quotational and Reference Accuracy in Surgical Journals*, 263 J. AM. MED. ASS'N 1353 (1990). Forty-eight percent (72) of the citations had some error, while nine percent (13) had major citation errors. Moreover, of the 137 articles with no major citation errors 23% (32) had major quotation errors, sometimes saying that a source supported a particular proposition, when it did not, as for example: "The article by Lowe is cited to support an increased risk of esophagal cancer with alcohol consumption. The article by Lowe is about treatment and contains absolutely no mention of etiology." *Id.*, at 1354.

[16] Inasmuch as the peer review system is conducted by human beings, there is no reason to expect it to be perfect, and it is not. This imperfection would not matter much if major errors were caught quickly and corrected completely. Even after a mistake is discovered, however, it can take *decades* to correct completely. Indeed, peer review journals seem unusually reluctant to acknowledge mistakes and to correct those mistakes that are conceded. For example, one contemporary probe recounts the saga of "unique cell cultures" that were the cause of much celebration when they were discovered a generation ago -- and great use and reliance by many scientists since that time. By the early 1970s, it was learned, though, that the putatively "unique" cultures were anything but. Nevertheless, those portions of the scientific community who were most responsible for the problems (and the ones best situated to rectify the errors) were decidedly reluctant to issue the necessary retractions. For this reason, it is believed that many scientists may still have not received the word and may yet be unaware of the contamination of the cell cultures. Michael Gold, A CONSPIRACY OF CELLS (1986).

More generally, according to a recent report by two investigators: "Little is known about the ultimate scientific fate of retracted, invalid literature. We identified 82 completely retracted articles . . . and measured their subsequent

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Both types of problems -- the initial failure to screen out faulty reports and the subsequent failure to adequately, if ever, inform readers that inaccurate or fallacious articles had been published -- are compounded by the fact that there is no licensing board that sets uniform criteria for what a journal should and should not publish or what a magazine needs to do to qualify as a peer review journal. Along the same lines, although professional basketball referees must go to school to learn what is or is not a foul, peer review journal referees receive no comparable training. Even more amazingly, the peer review industry is a wholly unregulated collection of completely independent and unsupervised periodicals, as there is no licensing board that certifies that a magazine qualifies as peer review journal. Like boilerroom "investment counselors" before the establishment of the Securities and Exchange Commission, calling oneself the editor of a peer review journal simply makes one so. At least, there is no entity to challenge such puffery.

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[16](...continued)
use in the scientific literature . . . . After retraction, these studies were cited, for support of scientific concepts, 733 times [or roughly nine times apiece.] Comparison with a control group revealed that retraction reduced subsequent citation by approximately 35% [only]." Abstract of Mark. P. Pfeiffer and Gwendolyn L. Snodgrass, *The Continued Use of Retracted, Invalid Scientific Literature*, 263 J. OF THE AMER. MED. ASS'N 1420 (1990). As a result, "[i]nvalid work is not being effectively purged from the scientific literature." *See also* Paul F. Friedman, *Correcting the Literature Following Fraudulent Publication*, 263 J. OF THE AMER. MED. ASS'N 1416 (1990).

IV. CONTRARY TO POPULAR OPINION, THE FACT THAT AN ARTICLE HAS BEEN PUBLISHED IN A PEER REVIEW JOURNAL DOES NOT ESTABLISH THAT THE FACTS, RESEARCH OR ANALYTICAL METHODOLOGIES, OR CONCLUSIONS REPORTED THEREIN ARE "GENERALLY ACCEPTED" BY OR REPRESENT THE "CONSENSUS" VIEWS OF THE RELEVANT SCIENTIFIC COMMUNITY

Peer review journals serve the scientific community in much the same way that legal periodicals and law reviews serve the legal community. For example, just as the SECURITIES LAW REPORTER recapitulates important new complaints, newly-promulgated SEC regulations, and new administrative law or court decisions, and just as law reviews offer summaries or analyses of new trends and developments and provide a forum for new theories or proposals, peer review journals recount significant new experiments, investigations, therapies, interpretations, and theories. But peer review journals are not like the "United States Reports" or "RESTATEMENTS OF THE LAW." Unlike the U.S. Reports, peer review journals do not provide the official accounts of authoritative decisions rendered by a body that is constitutionally ensconced and uniformly recognized as the preeminent arbiter of the law. For one thing, there is no Supreme Court of science -- no tribunal that has the power and authority to provide the final opinion on important controversies.[17] Similarly, unlike the RESTATEMENTS, peer review journals do not provide, either singly or collectively, the conclusive and exhaustive syntheses of what a college of the most

[17] Of course, as this Court well knows, no Supreme Court opinion is ever truly "final," at least in the sense that the subject cannot be revisited or that a precedent cannot be overturned. By like token, no Supreme Court decision is "absolutely right," in the sense that it cannot be reversed by a subsequent decision of the Court. Finally, no decision is "generally accepted," at least insofar as it is immune from criticism by everyone from Presidential candidates and elected officials to law professors and even justices of the Supreme Courts of the fifty states. To be sure, some decisions by this Court are unanimous and some decisions by this Court may become, sooner or later, "generally accepted." But few would wager when or if a decision will be generally accepted, and even if it becomes generally accepted, whether it will remain forever in that state of grace.

highly-regarded scholars, judges, and practitioners deem the law is (or ought to be). Furthermore, although there are some organizations of scientists, such as the National Academy of Sciences or the National Research Council, that are roughly comparable to the American Law Institute, the resolutions reached by the former, like RESTATEMENTS agreed upon by the latter, are not always published in peer review journals, nor are such resolutions the only things published in peer review journals.

To reiterate what was emphasized above, papers submitted to peer review journals for publication are accepted not because the peer review journals editors and referees have resolved that the information and ideas contained in the papers -- data, research protocols, analytical constructs, theoretical conclusions -- are necessarily true or immutably right or absolutely accurate or represent some form of scientific consensus, but because they have determined that the information and ideas are plausible and, thus, *may* contribute to the further development of scientific ideas.

Even this point must be qualified. The fact that the referees and editor of one journal have decided that the information and ideas contained in a submitted paper are plausible (or even the fact that they regard such ideas and information as absolutely true, universally valid, and unassailably accurate) does not mean that their judgment has been or would be shared by the editors and referees of other journals, that is, accepted by all or most of the scientific community. Indeed, the opposite may often be the case. A moment's reflection shows why this is so. Although it may well be that an article published in the NEW ENGLAND JOURNAL OF MEDICINE would have been accepted for publication by the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, and vice versa, the number of papers submitted to such prestigious journals is quite large and the number that is accepted is quite small. Although the publication acceptance rate varies from one discipline to another, as well from one journal to another, as a general rule, the more prestigious the journal, the greater are the number of papers submitted and the lower the percentage that are accepted.[18]

[18] In order "[t]o investigate disciplinary differences in how scientific journals evaluate submissions, [one researcher] collected data from the ASTRO-

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Understandably, most authors would prefer to see their articles published in JAMA than in the less renowned publication. Consequently, an author may first take a crack at getting published in JAMA and then, only if failing there, try to have his paper published in a slightly less celebrated journal, and on and on, until the quality of the paper has met its match in the quality of a journal. If the first journal rejects the submitted manuscript, it is sent on to next-best journal and so on, until either the article is published or the author relents. The number of bites at the apple is limited by only two factors: the number of journals in a relevant field and the size of the author's budget for postage. Thus, a

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PHYSICAL JOURNAL, PHYSIOLOGICAL ZOOLOGY, and the AMERICAN SOCIOLOGICAL REVIEW. Referees' evaluations of submissions to these journals differed strikingly: nearly half of the referee reports for American Sociological Review recommended outright rejection, while the corresponding proportions for the other two journals were about one fourth and one tenth. Final dispositions show even greater variation, with the ASTROPHYSICAL JOURNAL accepting 91% of submissions, PHYSIOLOGICAL ZOOLOGY 59%, and AMERICAN SOCIOLOGICAL REVIEW 13%." Abstract of Lowell L. Hargens, *Variation in Journal Peer Review Systems: Possible Causes and Consequences*, 263 J. OF AMER. MED. ASS'N 1348 (1990). *See also* Ann C. Weller, *Editorial Peer Review in US Medical Journals*, J. OF THE AMER. MED. ASS'N 1344, 1346 (1990) (acceptance rates for two broad categories of US medical journals range from 32.8% to 51.8%); Rick Crandall, *Peer Review: Improving Editorial Procedures*, BIOSCIENCE 607 (Oct. 1986)

> In fields like physics, which have acceptance rates of 80%, the rule of thumb [for referees and editors] is, "When in doubt, accept." After a second or third submission, most papers do get published. This high acceptance rate hides the lack of reliability and validity in the process. In fields like psychology, which have acceptance rates of about 20%, the number of papers [submitted] far exceeds the number of pages available. The rule here is, "When in doubt, reject." Those who know the game best enjoy far higher acceptance rates. Through apt choices of topics and methods and good contacts within one's research field, one can succeed.

manuscript may have been rejected by ten or twenty journals before it is finally accepted for publication by one.[19]

By this light, to suggest, as the Ninth Circuit did below, that the appearance of a paper in a peer review journal betokens "general acceptance" by a "consensus" of the scientific community is senseless. If anything, the numerous rebuffs that generally precede eventual acceptance connotes "general rejection" much more than a single endorsement manifests "general acceptance." (To assert or imply that all journals are equally rigorous is nonsense. Indeed, with the proliferation of peer review journals, it is axiomatic that getting a paper published somewhere, at some time, is a virtual certainty, if only one is willing to persevere.) Thus, by the time a paper is finally accepted by a single journal it may have been rejected by countless others.[20]

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[19] Unfortunately, there are few hard numbers on these questions. Although the overall acceptance/rejection rates for journals may be known, individual authors are understandably reluctant to disclose how many times their articles were rejected. By the same token, editors of less-renowned journals are unlikely to advertise the fact that they are in the business of publishing articles that have been rejected by a host of other, "better" journals and that they are, in a fashion, habitually dealing in shop-worn goods.

[20] In fact, whether a paper is accepted or rejected by single journal may depend more on fame or anonymity of the authors (or the relative prestige of the universities or other institutions with which the authors are affiliated) rather than on the quality of the author's work. Caprice and bias may play a much larger role than most champions of the peer review system would wish to acknowledge. *See* Daryl E. Chubin and Edward J. Hackett, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY 94 (1990). Thus, in an illuminating, if somewhat controversial study, two researchers resubmitted a series of twelve previously published articles to the "highly regarded and widely read American psychology journals," journals that had published the same articles 18 to 36 months earlier. The only difference between the articles that had been published and the articles that were resubmitted was that the names and affiliations of the "new" authors had been downgraded. Only three (different) resubmissions were caught, thus allowing nine manuscripts to continue through to the end of the review process. Amazingly, only one of the nine *articles that had been published previously* was accepted for publication the second time around. In each case, all reviewers agreed about the final disposition of the manuscript. But no one cited plausibility or lack of new results as reasons for rejection. In fact, most cited poor presentation or inadequacies in the methods as the rejection criteria. Douglas P.

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Peters and Stephen J. Ceci, *Peer-review Practices of Psychological Journals: The Fate of Published Articles, Submitted Again*, 5 BEHAV. AND BRAIN SCI. 187 (1982). Similar criticisms were offered in the study by Garfunkel, et al., *supra*. Steven Harnad, editor of PEER COMMENTARY ON PEER REVIEW, concludes (referring to the work of Peters and Ceci) that: ". . . any reader who thought that science was a matter of consensus should emerge from [reading the work of Peters and Ceci] thoroughly disabused of that notion. And lest be inclined to conclude that this outcome may pertain to particularly controversial material . . . let him sample other [author's] treatments. . .; nowhere will he find much evidence of univocality in important current work." Stevan Harnad, ed., PEER COMMENTARY ON PEER REVIEW: A CASE STUDY IN SCIENTIFIC QUALITY CONTROL 2 (1982). In another test, four researchers sent the same articles submitted to the JOURNAL OF GENERAL INTERNAL MEDICINE to different sets of reviewers. One member of each team was told the name and institutional affiliation of the author, while the second reviewer received the information "blind," *i.e.*, without information about the author's name and institutional affiliation. The researchers found that the "blind" reviews judged the article to be of a higher quality (and more deserving of publication) than did those reviewers who knew the author's name and affiliations. Robert A. McNutt, Arthur T. Evans, Robert H. Fletcher, and Suzanne W. Fletcher, *The Effects of Blinding on the Quality of Peer Review*, 263 J. AM. MED. ASS'N 1371 (1990). *See* Ann C. Weller, *Editorial Peer Reviews in US Medical Journals*, 263 J. OF THE AMER. MED. ASS'N 1344, 1346 (1990) ("prestige of author or [affiliated] institution" influenced the decisions of a sample of medical peer review journals to publish from 30.5% to 50% of the time).

Another investigator reviewed prior work on bias in peer review journals and concluded that the final disposition of a manuscript is influenced by the general stance of the conclusions (positive or negative), the prior publication records of the author(s), and other factors unrelated or weakly related to the quality of the research. Kay Dickersin, *The Existence of Publication Bias and Risk Factors for its Occurrence*, 263 J. AM. MED. ASS'N 1385 (1990). Additional evidence of bias on the basis of the size and magnitude of the reported effect and the size of the samples used can be found in many other studies. *See, e.g.*, Michael Mahoney, *Publication Prejudices: An Experimental Study of Confirmatory Bias in the Peer Review System*, 1 COGN. THER. AND RES. 161 (1977); Ina Spiegel-Rosing, *Science Studies: Bibliometric and Content Analysis* 7 SOC. STUD. SCI. 97 (1977); T.D. Sterling, *Publication Decisions and their Possible Effects on Inferences Drawn from Tests of Significance – or Vice Versa*, 54 J. AM. STAT. ASSOC. 34 (1959); T.C. Chalmers, R.S. Koff, and G.F. Grady, *A Note on Fatality in Serum Hepatitis*, 49 GASTROENT. 22 (1965); B. Sommer, *The File Drawer Effect and Publication in Menstrual Cycle Research*, 11 PSYCH. WOM. Q. 233 (1987); Von Bakanic, Clark McPhail, and Rita Simon, *The Manuscript Review and Decision-making Process*, 52 AM. SOC. REV. 631 (1987);
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These anomalies raise a troublesome question: if eventual publication by a single journal betokens "general acceptance", as has been claimed, what is the significance of previous rejections, particularly multiple rejections? If, as seems plausible, the rejection of a paper by a majority of the journals to which the paper had been submitted demonstrates general rejection, how can the publication of that paper by a presumably lesser-ranked journal magically transform it into a generally accepted one?[21] The answer to this conundrum is that courts should not attach too much significance (let alone dispositive weight) to the bare fact of publication (or non-publication). Surely, scientists do not. As participants in the peer review system, they realize that there is no simple, easy, foolproof, mechanical way of determining what is true and valid. They make judgments based on many factors.

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and C.B. Begg, and J.A. Berlin, *Publication Bias and Dissemination of Clinical Research*, 81 J. NAT'L CANCER INST. 107 (1989). In a particularly interesting study, one researcher reviewed 107 clinical trials of new therapies published in 1984 and found a correlation between the source of the funding and the direction of the results: 89% of the studies funded by pharmaceutical companies favored the new treatment versus 64% for studies not funded by pharmaceutical companies. R.A. Davidson, *Sources of Funding and Outcome of Clinical Trials*, 1 J. Gen. Intern. Med. 155 (1986). *See generally*, Daryl E. Chubin, *A Soap Opera for Science*, 37 BIOSCIENCE 259 (April 1987); Rick Crandall, *Peer Review: Improving Editorial Procedures*, BIOSCIENCE 607 (Oct. 1986); Chubin and Hackett, *supra*, at 8, 11-12, 94-103.

[21] The fallaciousnes of the argument that publication by one science peer review journal is tantamount to "general acceptance" by the entire scientific community, is best demonstrated by an analogy to the law. Imagine a litigant who won a favorable opinion from a single three-judge panel and then tried to stretch that isolated victory into a claim that his views were generally accepted by the entire legal community. If there were no other cases on point, the litigant might face no sanction harsher than being laughed out of court. If, on the other hand, his views had been presented to a number of courts of equal rank and, upon due consideration by those referees, had been rejected by each of those courts save one, a litigant's protestation that that a single acceptance somehow trumped all prior rejections might lead to sanctions a good bit more severe than derision. Similarly, one might reasonably wonder about the sense of a political candidate who insisted that victory in a single primary or endorsement by a single small-town paper constituted general acceptance by the entire electorate. Indeed, to state the proposition is to refute it.

They have few, if any, bright-line rules. In assessing the validity, or truth, or usefulness of an idea or datum, they may look to see if the idea or datum was published. But they rarely stop there. Instead, typically, they will look to see where it was published, who wrote it, what are their credentials, and so forth. It appears to us that courts should do no less.

V. JUST AS THE MERE FACT OF PUBLICATION DOES NOT SIGNIFY "GENERAL ACCEPTANCE", THE FACT OF NON-PUBLICATION DOES NOT INDICATE THAT IDEAS AND INFORMATION HAVE BEEN "GENERALLY REJECTED" OR THAT THEY ARE NOT AND CANNOT BE "GENERALLY ACCEPTED"

Scientists write, and seek to publish, papers for many reasons apart from the undiluted desire to report their insights and discoveries to the world: to gain tenure, attain promotions, acquire fellowships, win awards and honors, obtain funding for new projects, and retain funding for existing ones. The same ends -- including the broadcasting of new findings, ideas, and innovations -- can be accomplished in a number of different ways, including, but not limited to publishing articles in peer review journals.

There are at least four other ways in which scientists can introduce new ideas and information without publishing in peer review journals, ways that may be as least as effective, as least as impressive, and as least as well-established, legitimate, and well-regarded as publishing articles in peer review journals. *First*, scientists frequently are invited to give addresses at seminars, conferences, and colloquia; the printed versions of these speeches are usually reprised in the printed proceedings or reports of those conferences.[22] Although the speeches are not formally peer

[22] Sometimes speeches, or their content, find their way into textbooks which, interestingly, are not formally peer reviewed. They are usually informally read by friends of the authors, who make suggestions and are acknowledged in the prefaces. Multi-author texts, which are common in the biomedical sciences, are overseen by one or more editors but these individuals cannot possibly be (continued...)

reviewed either before or after they are delivered, the fact the authors were selected by their peers as speakers serves much the same quality control function.[23] ***Second***, "electronic bulletin boards" similarly offer instant dissemination by the authors -- and, ofttimes, instant questioning and critiques by those scientists who regularly peruse these electronic colloquia.

Third, reports and studies generated by and for federal, state, and local governmental agencies (and proposals submitted to such agencies by researchers seeking grants) likewise provide a way for scientists to exchange ideas and information. As noted in the National Research Council's recent study on so-called "Gray Literature," ENVIRONMENTAL EPIDEMIOLOGY: HEALTH AND HAZARDS (1991), government agencies rely heavily, indeed, at times almost exclusively, on such reports, notwithstanding the fact that they are not published in peer review journals. ***Finally***, private industry, corporate research consortia, and independent think tanks correspondingly commission the same sort of reports and studies from both staff scientists and independent consultants and rely on them just as heavily as government agencies, despite the fact that, once again, these papers are not formally published in peer review journals.

Some of the reports thus generated, whomever the sponsor and whatever the forum, are "pure or basic science," in the sense that they have no immediate and specific application; these

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sufficiently expert in all the areas discussed in the text and, thus, cannot exercise any penetrating review of each part.

[23] In fact, authors who present such papers may be prevented from publishing their papers in peer review journals because of professional jealousies between, for example, research foundations and peer review journals. Thus, on the one hand, powerful funding establishments, like the Howard Hughes Medical Institute or the Robert Wood Johnson Foundation, reprint papers presented at fora they sponsor in the newsletters or magazines they publish. This practice can have the effect of preventing the same paper (and, occasionally, even the sequelae written by the same presenter) from being published in a peer review journal because some peer review journals, such as the NEW ENGLAND JOURNAL OF MEDICINE adamantly refuse to publish reports that first saw the light of day anywhere else -- be it at a public seminar, a private roundtable, or a televised news conference.

scholarly reports most closely approximate the pristine studies that are the ideal of peer review journals. Other studies and reports may lie closer to opposite extreme of "applied science," that is, utilitarian accounts that are generated in response to particular technical questions or specific technological or biomedical problems -- such as queries about the safety of a bridge design, evaluations of best location of a gas tank in a new car, predictions of how a new airport would affect highway traffic, or estimations of the side-effects of a new pharmaceuticals.

Perhaps the paradigmatic examples of high quality science that is almost never published are medical evaluations of particular patients with a specific disease. In such a situation, the questions are distinctively practical ones -- whether, for example, to treat a malignancy with radiation or chemotherapy. Yet, whether the work undertaken yields a new, theoretical advance in basic science or results in new, practical applications of venerable principles and regardless of whether the ideas are presented in a seminar or dictated into surgical notes, scientists will assess them on the basis of what they say and how they say it and how useful they are, and not on where and whether they were peer reviewed ahead of time. The fact remains that some of the best science is the most specific science. Most importantly, this sort of science may not be publishable not because it is wrong, or outside the mainstream of generally accepted views, but simply because a peer review journal editor might decide that it would not be of sufficient interest to enough of her subscribers.[24]

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[24] Nevertheless, even if an author aimed to publish the results of his or her research in a peer review journal and even if the none of impediments identified above barred his way, others barriers might. ***First***, a paper topic might be preempted by a virtually identical paper written by a different author. (Anyone who has had the misfortune of having a law review note topic preempted in the same fashion might empathize with the frustration endured by the Johnny-come-lately). ***Second***, even if a paper topic is not preempted, the author's time might be -- by anything from the exigencies of a personal crisis or a career move to being pulled from one topic to another, either by the entreaties of one's superiors or the lure of an intrinsically more interesting area of research or both. Because academic promotion and tenure decisions are strongly influenced by "publication counts," faculty members who wish to advance in their profession often feel intense pressures to publish. Even so, on occasion, some good research goes

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To be sure, corporations, think tanks, and litigants who commission studies and reports all want reports that suit their needs -- and their wishes are often fulfilled. This seems unremarkable. For this reason, courts need be skeptical of reports that were prepared and paid for by the partisans to a dispute, whether that dispute involves a patent fight between two inventors, a contract dispute between two corporations, or, as in the case before the

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unsubmitted or unpublished because graduate students and postdoctoral fellows (who take on a disproportionate share of the actual research) may leave for another school or lab before writing up their results. In other instances, research may go unpublished because the scientists get distracted by even more exciting discoveries (and the promise of more prestige or bigger research grants) and thus simply never get around to finishing old (and, by then, boring) manuscripts.

Competitive pressures may enter into decision of whether and when to publish in other ways. To cite but two examples, a researcher who learns that a competitor is close to publishing results of comparable research experiments may hasten to send his own manuscript to the editors of various journals in order to head off his colleague and thus to seize from her both the glory and the accompanying riches. On the other hand, another researcher who learns that a competitor is struggling with balky equipment that the first researcher has mastered, may hesitate to publish his research for fear that his explanation of how he obtained his results will enable his competitor to correct her errors and catch up. ***See generally***, James Watson, THE DOUBLE HELIX (1977) (describing the hunt to discover DNA that led to author's Nobel Prize, his team's heated rivalry with Nobel laureate Linus Pauling, and the various stratagems they employed to throw Pauling off the trail.)

Third, there is the problem of bias: (1) bias against some authors and schools, *id.*; (2) bias in favor of other authors and other institutions, *id.*; (3) bias against negative results, Dickersin, *supra*; (4) bias against particular results, *see, e.g.*, Boyce Rensberger, "DNA 'Fingerprinting' Is Disputed," Washington Post, Dec. 20, 1991, at A3 and "***'Science' Editor Denies Yielding to FBI Pressure***," SCIENCE & GOVERNMENT REPORT, Feb. 15, 1992, at 1; (5) bias against truly innovative ideas, *see, e.g.*, ***"Science Beyond the Pale"***, 249 SCIENCE 14 (July 1990) and *see, generally*, Thomas S. Kuhn, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (2d ed. 1970); and (6) bias against nuts-and-bolts "clinical research," as opposed to more ethereal "theoretical research." As to the last point, one researcher studied patterns associated with the publication of the results of clinical trials and concluded that the full reporting of the results of clinical trials is very irregular. "Substantial numbers of clinical trials are never reported in print, and among those that are, many are not reported in sufficient detail to enable judgements to be made about the validity of their results." Ian Chalmers, ***Underreporting Research Is Scientific Misconduct***, 263 J. AM. MED. ASS'N 1405 (1990).

Court, a tort suit between the manufacturer and consumers of a product. Moreover, it should not matter whether the report was prepared on the eve of a trial or prepared years earlier, not in preparation for a specific case, but generally in anticipation of litigation. Thus, experts who rely on non-published materials and who otherwise display no independent cast of mind or scholarship should be subject to close questioning (just like other experts); they should not be barred outright from testifying, however, lest the Court be willing to write off as tainted and unreliable every study and report that has not been published in a peer review journal. Not only is the peer review system less reliable as a quality control system -- in publishing only the good and in weeding out all of the bad -- than is commonly thought, but the efficacy of cross-examination hardly suffers in comparison the peer review system. Indeed, as discussed below, cross-examination suffers not at all in comparison.

VI. THE PEER REVIEW SYSTEM IS NOT MORE RIGOROUS AND MORE RELIABLE THAN THE LEGAL SYSTEM'S USE OF CROSS-EXAMINATION

Some observers have advanced the notion that the peer review system is much more rigorous and thereby more likely to reveal truths and uncover falsehoods than cross-examination. As noted above, some of the amici have not only participated in the peer review system as authors, referees, and editors but have also observed the legal system at close range, most specifically as expert witnesses who have endured cross-examination at depositions and trial. To put it bluntly, those amici who have personal experience with both systems find the notion that peer review is more strenuous and exacting than cross-examination completely mistaken.

The myth that peer review journals provide rigorous scrutiny of submitted papers is largely based on the underlying fable that peer review editors and referees replicate the experiments and analyses discussed in those papers. As noted above, they do not. Indeed, the meager amount of time spent by unpaid volunteer referees in reviewing submitted manuscripts hardly allows for

painstaking replication or other forms of rigorous scrutiny. It is a little-known but well-established fact (ironically, well-established in the peer review literature) that the average time spent on a review ranges between "less than" 2.0 hours and 2.4 hours, depending on the study. *See* n. 11, *supra*.

By contrast, cross-examination often subjects a witness to scrutiny that is longer-lasting, more intensive in depth, and more extensive in the breadth of subjects examined. ***First***, there are rarely time limits placed on cross-examination itself (and as most expert witnesses will attest, they must spend at least as much time preparing their testimony and explaining what it is all about to the lawyers who have hired them as they do on the witness stand.) ***Second***, once on the witness stand, a witness may be obliged to endure a line-by-line exegesis of his article and asked to explain and defend every point. ***Third***, the questions asked on cross-examination are not mercifully limited to the specific parameters of the paper or report that is the foundation of the expert's conclusion; instead, almost anything the expert has done, said, or written is fair game. For example, on cross-examination an expert witness can be subject to close questioning not only on the basis of the specific sources of his or her testimony, but can be impeached by anything he or she had said or written that is potentially inconsistent. His or her motives and credentials can be scrutinized in ways unimaginable to peer review editors and referees. The peer review system has nothing comparable. All in all, whatever the pressures are generated by the peer review system, cross-examination is, quite literally, a far more trying experience.

It is not often that scientists, sociologists, and historians have occasion to comment on the virtues of the legal system. In this case, however, it seems that the Court should take to heart its own admonitions about the value of cross-examination:

> The opportunity for cross-examination . . . is critical for ensuring the integrity of the fact-finding process. Cross-examination is "the principal means by which the believability of a witness and the truth of his testimony are tested." Indeed, the Court has recognized that *cross-examination is the "'greatest legal engine ever invented for the discovery of truth.'"*

Kentucky v. Stinger, 482 U.S. 730, 736 (1987) (citations omitted; emphasis added).

CONCLUSION

For the reasons stated above, the *amici* respectfully urge the Court to reverse the judgment of the United States Court of Appeals for the Ninth Circuit in this matter.

Respectfully submitted,

Ran Simon, Esq.
Connerton, Ray and Simon
1920 L Street, N.W.
Suite 400
Washington, DC 20036
202/466-6790
Counsel of Record for Amici Curiae Daryl E. Chubin, Edward J. Hackett, David M. Ozonoff, and Richard W. Clapp

Nicole Schultheis, Esq.
Nicole Schultheis, P.A.
201 N. Charles Street
Suite 1630
Baltimore, MD 21201
410/547-1771

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APPENDIX

DETAILED DESCRIPTION OF THE QUALIFICATIONS OF, AND POSITIONS HELD BY THE *AMICI CURIAE*

Daryl E. Chubin is Senior Associate in the Science, Education, and Transportation Program, Office of Technology Assessment (OTA), U.S. Congress, where he has worked since 1986. Prior to coming to the OTA, Chubin was a full professor in the School of Social Sciences at the Georgia Institute of Technology, where he directed that school's Masters Program in Technology and Science Policy. He previously taught at Cornell University and the University of Pennsylvania. He received his Ph.D. in sociology from Loyola University, Chicago, in 1973 and was elected a Fellow of the American Association for the Advancement of Science (AAAS) in 1990. He has consulted for various divisions of both the National Academy of Sciences and the National Institutes of Health, the AAAS, the National Research Council, the American Chemical Society, as well as several private corporations and a number of non-profit organizations. He currently serves in an editorial capacity for five peer review journals (including for SOCIAL STUDIES OF SCIENCE, SCIENCE AND PUBLIC POLICY, BIOSCIENCE, and SCIENCE, TECHNOLOGY & HUMAN AFFAIRS), has been published in numerous peer review journals (including the aforementioned journals as well as SCIENCE, THE SCIENTIST, and CHRONICLES OF HIGHER EDUCATION) and is also the author of studies and reports that have been presented at various academic colloquia. He is the author of five books (including THE CANCER MISSION: SOCIAL CONTEXTS OF BIOMEDICAL RESEARCH (1980, co-authored); INTERDISCIPLINARY ANALYSIS AND RESEARCH (1986, co-edited), and SCIENCE OFF THE PEDESTAL: SOCIAL PERSPECTIVES ON SCIENCE AND TECHNOLOGY (1989, co-edited)). His most recent book, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990), which he co-authored

with fellow amicus Edward J. Hackett, has been hailed as the most definitive book on the peer review system.

Edward J. Hackett is an Associate Professor in the Department of Science and Technology Studies at the Rensselaer Polytechnic Institute, where he has taught since 1984. He received his Ph.D in sociology from Cornell University in 1979. Among his many honors, he received a Postdoctoral Fellowship from the National Institutes for Mental Health. He has served as a book review editor for SCIENCE, TECHNOLOGY & HUMAN VALUES (STHV), and as a peer review referee for eight other journals, as well as a reviewer for the National Science Foundation (NSF) and as a member of grants peer review panels for the National Endowment for the Humanities. He has served as a speaker on NSF and AAAS programs and is the author of nine published articles. He is the coauthor, along with fellow amicus Daryl J. Chubin, of PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990), which has been hailed as the most definitive book on the subject.

David Michael Ozonoff is presently the Chair of the Department of Environmental Health at the Boston University School of Public Health and Professor of Public Health as well as a Professor in the Department of Socio-Medical Science and Community Medicine at the Boston University School of Medicine. He has also lectured at, and directed the Concourse Program in the Department of the Humanities at, the Massachusetts Institute for Technology (MIT), worked as a Research Associate in the Department of History of Science at Harvard University, and served in the Office of Science and Technology at the World Health Organization. Dr. Ozonoff has served as an member of, or adviser to, various governmental bodies including the U.S. Department of Health and Human Services, the U.S. Environmental Protection Agency, the National Academy of Sciences, the

National Research Council, the U.S. Congress' Office of Technology Assessment, the Government Accounting Office, the Massachusetts Department of Public Health, the Massachusetts Department of Environmental Quality Engineering, the City of Boston's Department of Health and Hospitals, and the Boston School Department. He has additionally served as a consult to number private corporations and research establishments. Dr. Ozonoff has contributed chapters and essays to seven books, including the TEXTBOOK OF INTERNAL MEDICINE AND PRIMARY CARE, J. Noble, ed. (1987); MOLECULAR DOSIMETRY AND HUMAN CANCER: ANALYTICAL, EPIDEMIOLOGICAL AND SOCIAL CONSIDERATIONS, J. Groopman and P. Skipper, eds., (1991); GENETIC ALCHEMY: A SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY, S. Krimsky, ed. (1982); HAZARDOUS WASTE DISPOSAL: ASSESSING THE PROBLEM, J.H. Highland, ed. (1982); and GENETICS AND THE LAW, III, A. Milunsky and G. Annas, eds. (1985). He is the author of 67 other scholarly papers and reports, including articles published in the NEW ENGLAND JOURNAL OF MEDICINE, THE AMERICAN JOURNAL OF PUBLIC HEALTH, THE ENCYCLOPEDIA BRITANNICA HEALTH AND MEDICAL ANNUAL, THE INTERNATIONAL JOURNAL OF EPIDEMIOLOGY, TERATOGENESIS, CARCINOGENESIS, AND MUTAGENESIS, HEALTH PHYSICS, AND CANCER IMMUNOLOGY AND IMMUNOTHERAPY, THE INTERNATIONAL JOURNAL OF HEALTH SERVICES, THE AMERICAN JOURNAL OF FORENSIC MEDICINE AND PATHOLOGY, THE AMERICAN JOURNAL OF INDUSTRIAL MEDICINE, AND TECHNOLOGY REVIEW. He serves as a consulting editor for the AMERICAN JOURNAL OF EPIDEMIOLOGY as well as in the same editorial capacity for the ARCHIVES OF ENVIRONMENTAL HEALTH. He earned his M.D. from Cornell University Medical College in 1967 and his M.P.H. from the Johns Hopkins School of Hygiene and Public Health in 1968. He has received awards from MIT, Harvard University, the John Hopkins University, and the Lund Institute of Technology Finally, he has served as an expert witness, and has testified at trials and/or depositions in more than 100 cases.

Richard W. Clapp has served as the Director of the Center for Environmental Health Studies for John Snow, Inc. in Boston since 1989. From 1980 through 1989, he served as the Director of the Massachusetts Cancer Registry, a division of the Massachusetts Department of Health. He currently is also an Assistant Clinical Professor at Tufts University School of Medicine and an Adjunct Assistant Professor at Boston University School of Public Health. He received his M.P.H. from the Harvard School of Public Health in 1974 and his Sc.D. in Epidemiology from the Boston University School of Public Health in 1989. He is a member of the American Public Health Association, the American College of Epidemiology, the Society of Epidemiologic Research, and the International Society of Environmental Epidemiology. He has published articles in such peer review journals as Cancer, the International Journal of Epidemiology, and the Journal of the American Academy of Dermatology, as well as having presented papers to assemblages of the American Public Health Association and other scholarly organizations. He presently serves on the editorial advisory board of NEW SOLUTIONS: A JOURNAL OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH POLICY JOURNAL. He has also given testimony at numerous trials and depositions.